Supreme Court, U.S.
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No.

In the Supreme Court of the United States

OCTOBER TERM, 1996

DAVID A. KESSLER, M.D.,
COMMISSIONER OF FOOD AND DRUGS, AND
BRUCE A. LEHMAN, ASSISTANT SECRETARY OF
COMMERCE AND COMMISSIONER OF PATENT AND
TRADEMARKS, CROSS-PETITIONERS

v.

ORGANON, INC., BRACCO DIAGNOSTICS INC. AND
BRACCO INTERNATIONAL B.V., ET AL.

*ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT*

CROSS-PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

The 1994 Uruguay Round Agreements Act (URAA) establishes a new patent term of 20 years from the date on which the patent application was filed. 35 U.S.C. 154(a)(2). The transitional provision of the URAA provides that "[t]he term of a patent that is in force on or that results from an application filed before [June 8, 1995] shall be the greater of the 20-year term as provided in subsection (a) or 17 years from grant, subject to any terminal disclaimers." 35 U.S.C. 154(c)(1).

The question presented by this petition is whether the court of appeals erred in declining to uphold the determination of the Commissioner of Patents and Trademarks that, with respect to patents affected by the transitional provision of the Uruguay Round Agreements Act (URAA), 35 U.S.C. 154(c)(1), extensions granted under the Hatch-Waxman Act, 35 U.S.C. 156, cannot be added to the URAA's newly-created 20-year patent term.

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The Solicitor General, on behalf of David A. Kessler, M.D., Commissioner of Food and Drugs, and Bruce A. Lehman, Assistant Secretary of Commerce and Commissioner of Patents and Trademarks, respectfully conditionally cross-petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case. If the Court grants the petition in either

No. 96-562 or 96-575, it also should grant this petition. If the Court denies both of those petitions, this cross-petition also should be denied.

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-23a)[1] is reported at 80 F.3d 1543. The opinion of the district court in No. 96-575 (Pet. App. 28a-39a) is reported at 903 F. Supp. 964. The opinion of the district court in No. 96-562 (Pet. App. 24a-27a) is unreported. The district court's orders on remand from the court of appeals' decision (Pet. App. 40a-41a; 96-575 Pet. App. 29a-34a) are unreported.

JURISDICTION

The judgment of the court of appeals (Pet. App. 92a-94a) was entered on April 4, 1996, and its mandate was issued on July 19, 1996. The federal parties' petition for rehearing was denied on July 12, 1996. Pet. App. 80a-91a. A petition for a writ of certiorari was filed by Organon, Inc. (No. 96-562) on October 9, 1996, and was placed on this Court's docket on the same day. A petition for a writ of certiorari was filed by Bracco Diagnostics Inc. and Bracco International B.V. (No. 96-575) on October 10, 1996, and was placed on this Court's docket on October 15, 1996. This conditional cross-petition is filed pursuant to Rule 12.5 of this Court. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

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[1] Unless otherwise indicated, Pet. App. refers to the Appendix in No. 96-562.

STATEMENT

The facts and proceedings are set forth in the brief in opposition of the federal parties filed in Nos. 96-562 and 96-575.

REASONS FOR GRANTING THE CROSS-PETITION

As explained in the brief in opposition of the federal parties filed in Nos. 96-562 and 96-575, this case does not present issues of sufficient public importance to warrant this Court's review. The case involves a transitional provision of the URAA, and thus has only a temporally limited significance.

If this Court were to grant the petition in either No. 96-562 or 96-575, however, its review of the questions presented in either or both of those petitions also should encompass the error of the court of appeals in failing to defer to the reasonable interpretation of the Commissioner of Patents and Trademarks concerning the availability of patent term extensions to transition period patent holders. As set forth in the PTO's Final Determination (Pet. App. 56a-66a), the Commissioner, after notice and comment, determined that, with respect to patents in force on, or that resulted from an application filed before, June 8, 1995 (the effective date of the URAA), extensions granted under the Hatch-Waxman Act, 35 U.S.C. 156, could be added only to the original term of 17 years from the date of the patent's issuance, and not to URAA's newly created 20-year patent term. Under PTO's decision, a transition period patent holder is entitled to the greater of (i) 17 years from the date of the patent's issuance plus the Hatch-Waxman extension or (ii) a term of 20 years from the date of the patent application.

The court of appeals acknowledged that "Congress did not expressly address the question whether a restoration extension under section 156 could be added to the term of a patent which could also invoke the section 154 transitional provision." Pet. App. 8a. In declining to defer to PTO's Final Determination, the court of appeals acted contrary to this Court's repeated admonition that "if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843 (1984).

The court of appeals justified its refusal to accord *Chevron* deference to PTO's statutory interpretation because "Congress has not vested the Commissioner with any general substantive rulemaking power." Pet. App. 13a-14a. That reasoning is contrary to this Court's decisions requiring deference to an agency's reasonable interpretation of a statute that the agency administers or enforces. See *Clarke* v. *Securities Indus. Ass'n*, 479 U.S. 388, 403 (1971) ("It is settled that courts should give great weight to any reasonable construction of a regulatory statute adopted by the agency charged with enforcement of that statute.") (quoting *Investment Co. Institute* v. *Camp*, 401 U.S. 617, 626 (1971)); see also *Smiley* v. *Citibank (South Dakota), N.A.*, 116 S. Ct. 1730, 1733 (1996) ("It is our practice to defer to the reasonable judgments of agencies with regard to the meaning of ambiguous terms in statutes that they are charged with administering."); *NationsBank of North Carolina, N.A.* v. *Variable Annuity Life Ins. Co.*, 115 S. Ct. 810, 813 (1995) (*Chevron* deference given to Comptroller of the Currency's interpretation of a statute

the agency administered and applied in an adjudication).[2] The court of appeals' failure to accord proper deference to PTO's Final Determination led to an erroneous interpretation of the statute and to a result not advocated by any of the parties to this case.

1. Congress has declared that "[t]he Commissioner [of the Patent and Trademark Office] * * * shall superintend or perform all duties required by law respecting the granting and issuing of patents." 35 U.S.C. 6(a). Under that grant of authority, PTO promulgated its Final Determination to carry out its statutory duty to determine whether patent holders

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[2] Moreover, the court of appeals' refusal to defer to the PTO's Final Determination conflicts with many court of appeals' decisions that defer to an agency's reasonable interpretation of a statute it administers. See, *e.g.*, *Wagner Seed Co.* v. *Bush*, 946 F.2d 918, 922 (D.C. Cir. 1991) ("it simply is not the law of this circuit that an interpretive regulation does not receive the *Chevron* deference accorded a legislative regulation"), cert. denied, 503 U.S. 970 (1992); *Midtec Paper Corp.* v. *United States*, 857 F.2d 1487, 1496-1497) (D.C. Cir. 1988) (deference due to a permissible agency interpretation whether it arises out of rulemaking or adjudication); *American Land Title Ass'n* v. *Clarke*, 968 F.2d 150, 154 (2d Cir. 1992) (rejecting argument that pronouncement of Office of Comptroller of the Currency is not entitled to deference because it took the form of an interpretive rule rather than a legislative regulation), cert. denied, 508 U.S. 971 (1993); *Kennedy* v. *Shalala*, 995 F.2d 28, 30 n.3 (4th Cir. 1993) ("[t]hough the interpretive ruling at issue here does not itself have the force and effect of law or regulation, it is nonetheless entitled to deference as the Secretary's interpretation of a statute she is charged with administering"); *Satellite Broadcasting & Communications Ass'n of America* v. *Oman*, 17 F.3d 344 (11th Cir.) (Copyright Office's interpretive rules upheld as not arbitrary, capricious, or in conflict with the clear meaning of the statute), cert. denied, 115 S. Ct. 88 (1994).

affected by the transitional provisions of the URAA are entitled to Hatch-Waxman extensions. When a patent holder submits an application for a Hatch-Waxman Act extension, the Commissioner must determine the length of that extension. 35 U.S.C. 156(c) and (e). In making that determination, the Commissioner must ensure that the extension, when added to the period remaining in the term of the patent, does not exceed 14 years from the date of FDA approval of the drug. 35 U.S.C. 156(c)(3). Accordingly, for a transitional patent holder, the Commissioner necessarily must ascertain eligibility for, and length of, an extension by first determining whether the extension is added to the 17-year-from-grant term or the 20-year-from-application term.[3] Hence, in concluding that for transitional patent holders a Hatch-Waxman Act extension may be added only to the 17-year term, PTO's Final Determination interpreted legal provisions that PTO necessarily must apply in carrying out the statutory duties that Congress entrusted to the agency.[4]

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[3] Other determinations that PTO must make in granting extensions under Section 156 include: (1) whether the patent has expired (35 U.S.C. 156(a)); (2) whether the patent has previously been extended under Section 156(e) (35 U.S.C. 156(a)); (3) whether the product has been subject to a regulatory review period before its commercial marketing or use (35 U.S.C. 156(a)); (4) whether the application for the extension was submitted within 60 days of the date on which the product received permission for commercial marketing or use (35 U.S.C. 156(d)(1)); and (5) whether the patent is eligible for an extension (35 U.S.C. 156(e)).

[4] The expiration date of a patent term relates to other statutory duties of the PTO, including its obligation to determine (1) whether to initiate an interference proceeding (35 U.S.C. 135 ("[w]henever an application is made for a patent

2. Under *Chevron*, 467 U.S. at 843, courts are required to defer to an agency's reasonable construction of a statute that it administers if Congress has not addressed the precise question at issue. Although it is undisputed that "Congress did not expressly address the question" at issue in this case (Pet. App. 8a), the court of appeals refused to accord deference to PTO's interpretation because PTO has no rulemaking authority. Pet. App. 13a-14a.[5]

The court of appeals' ruling is based on the notion that because PTO's Final Determination is an interpretive rather than a legislative rule, the statutory construction issue may be decided *de novo*.[6] That rationale finds support in *EEOC* v. *Arabian American Oil Co.*, 499 U.S. 244 (1991), in which the Court concluded that because Congress did not confer

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which, in the opinion of the Commissioner, would interfere with any pending application, or with *any unexpired patent*, an interference may be declared") (emphasis added)); (2) whether a patent is eligible for reexamination (37 C.F.R. 1.510(a)); and (3) whether a patent is eligible for reissuance (*In re Morgan*, 990 F.2d 1230 (Fed. Cir. 1993) (under 35 U.S.C. 251, the Commissioner cannot reissue a patent whose term has expired)).

[5] The district court concluded that no deference was due to the PTO in "a straightforward matter of statutory interpretation." Pet. App. 34a. This Court specifically has rejected, however, the proposition that *Chevron* deference is inapplicable to "a pure question of statutory construction." *NLRB* v. *United Food & Commercial Workers Union*, 484 U.S. 112, 123 (1987).

[6] The court relied on earlier precedent that PTO's authority under 35 U.S.C. 6(a) to "establish regulations, not inconsistent with law, for the conduct of proceedings in the Patent and Trademark Office" did not grant PTO "the authority to issue substantive rules." Pet. App. 13a.

upon the EEOC authority to promulgate rules and regulations, "the level of deference afforded 'will depend upon * * * all those factors which give [the agency] power to persuade, if lacking power to control.'" 499 U.S. at 257 (quoting *Skidmore* v. *Swift & Co.*, 323 U.S. 134, 140 (1944)). In his concurring opinion, Justice Scalia expressed the view that "the 'legislative rules vs. other action' dichotomy" is an "anachronism" "[i]n an era when our treatment of agency positions is governed by *Chevron*." 499 U.S. at 260 (Scalia, J., concurring). Indeed, this Court's recent unanimous decision in *NationsBank of North Carolina, N.A.* v. *Variable Annuity Life Ins. Co.*, *supra*, applied *Chevron* deference to an agency adjudication and held that "[i]f the administrator's reading fills a gap or defines a term in a way that is reasonable in light of the legislature's revealed design, we give the administrator's judgment 'controlling weight.'" 115 S. Ct. at 813-814.[7] The Court has long applied a similar approach to interpretations of the agency's governing statute adopted in the course of adjudications by the National Labor Relations Board, which has seldom utilized its rulemaking authority. See, *e.g.*, *NLRB* v. *Town & Country Elec., Inc.*, 116 S. Ct. 450, 453 (1995). We sub-

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[7] Even the case upon which the court of appeals primarily relies—*Atchison, T. & S. F. Ry.* v. *Peña*, 44 F.3d 437, 441-442 (7th Cir. 1994) (en banc), aff'd, 116 S. Ct. 595 (1996)—gave "weight" to the Federal Railroad Administration's interpretive rule. Moreover, in that case the agency abandoned its long-established interpretation of a statute, and, to promote uniformity, adopted the interpretation given to the statute by the Ninth Circuit, even though the agency disagreed with that ruling. In those circumstances, which are not present here, the court declined to give *Chevron* deference to the agency's rule.

mit that, as an interpretative application of governing legal provisions charged to the agency's administration, PTO's Final Determination in this case is similarly entitled to substantial weight. Congress has not addressed the "combined effects of the URAA and the Hatch-Waxman Act for patents issued prior to June 8, 1995." Pet. App. 8a. PTO's Final Determination addresses that question and reasonably interprets those two statutes.

3. According due deference, the court of appeals should have accepted the statutory interpretation set forth in PTO's Final Determination. Under Section 156 of the Hatch-Waxman Act, extensions run "from the original expiration date of the patent." 35 U.S.C. 156(a). That term is not defined in the statute. PTO's determination that it means the "date on which the patent, *when granted*, was set to expire" (Pet. App. 59a (emphasis added)) is reasonable and in accord with the plain meaning of the statutory language. Reasonably interpreting the term "original expiration date" to describe only the end of the original 17-year from issuance term, PTO logically concluded that, for transitional patents in force on June 8, 1995, Hatch-Waxman extensions are not added to the URAA's newly created 20-year term, because the original expiration date of transitional patents is fixed at the time the patents were issued—17 years from grant—and cannot be shifted to the end of the new 20-year term.

In ruling *de novo* that the term "original expiration date" means "no more than that the expiration date has not been extended under section 156(e)(1) and, thus, the phrase can identify more than one date" (Pet. App. 17a), the court of appeals relies on a letter from Congressman Tom Railsback for the proposition

that the phrase "original expiration date" simply ensures that a patent does not receive a second Hatch-Waxman extension. That letter, however, does not address the specific provision at issue, but addresses a bill that was not enacted into law and that did not contain the current provision of the Hatch-Waxman Act that allows patent extensions only if "the term of the patent has never been extended under subsection (e)(1) of this section." 35 U.S.C. 156(a)(2). The current language makes the interpretation reflected in the Railsback letter superfluous.[8]

Finally, PTO's ruling reconciles and fully effectuates the two statutory provisions at issue while avoiding problems created by the court of appeals' decision. For example, the court of appeals recognized that under its interpretation, "[i]n some instances, there may be a problem in adding a restoration extension granted pre-URAA to the 20-year term" because "[u]nder the Hatch-Waxman Act [Section 156(c)(3)] the patent term plus any restoration extension cannot exceed 14 years from the date of FDA approval." Pet. App. 17a-18a. Instead of

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[8] Furthermore, the court erred in relying on the URAA amendment that added to Section 156(a)(2) the phrase "under subsection (e)(1)." Pet. App. 16a-17a. Prior to that amendment, Section 156(a)(2) required that "the term of the patent had never been extended" in order for the patent to be eligible for an extension under Section 156. Because the URAA added new extensions to account for delays in the issuance of a patent due to a successful appeal of adverse PTO decisions or for delays caused by patent interference proceedings, 35 U.S.C. 154(b), an amendment to Section 156(a)(2) became necessary to make clear that an extension under Section 154(b) does not preclude a Hatch-Waxman extension pursuant to Section 156. The amendment to Section 156(a)(2) simply prevents that unintended result, and does not address the question at issue here.

deferring to PTO's reasonable interpretation of the statute that would have avoided that "problem" altogether, the court of appeals observed that "[c]orrection to fit within the 14-year limitation entails only a purely ministerial task." *Id.* at 18a. That approach, however, finds no support in the statute.[9]

CONCLUSION

If the Court grants the petition in No. 96-562 or 96-575, it also should grant this petition. If the Court denies both of those petitions, this cross-petition also should be denied.

Respectfully submitted.

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NOVEMBER 1996

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[9] The court of appeals also noted (Pet. App. 19a) the "[m]ore troubling * * * problem of fitting together the different limitations on remedies during successive extensions," a problem that would also be alleviated by PTO's determination that Hatch-Waxman Act extensions cannot be added to URAA's new 20-year term for transitional patents.